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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Sylvestre Marillonnet

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EXAMINER

WORLEY, CATHY KINGDON

ART UNIT

PAPER NUMBER

1638

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/578,962	<b>Applicant(s)</b> MARILLONNET ET AL.	
	<b>Examiner</b> CATHY K. WORLEY	<b>Art Unit</b> 1638	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-57 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-57 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 3-5 and 13, drawn to a stably transformed plant, plant part, or plant cell culture containing heterologous DNA having a sequence encoding an RNA replicon derived from a plant RNA virus and comprising a sequence of interest to be expressed from said RNA replicon; wherein selected localities of said RNA virus are localities of high A/U content.

Group II, claim(s) 6, drawn to a stably transformed plant, plant part, or plant cell culture containing heterologous DNA having a sequence encoding an RNA replicon derived from a plant RNA virus and comprising a sequence of interest to be

Art Unit: 1638

expressed from said RNA replicon; wherein cryptic splicing sites flanking A/U-rich regions have been removed.

Group III, claim(s) 7 and 8, drawn to a stably transformed plant, plant part, or plant cell culture containing heterologous DNA having a sequence encoding an RNA replicon derived from a plant RNA virus and comprising a sequence of interest to be expressed from said RNA replicon; wherein there is an insertion of one or more nuclear introns.

Group IV, claim(s) 9, drawn to a stably transformed plant, plant part, or plant cell culture containing heterologous DNA having a sequence encoding an RNA replicon derived from a plant RNA virus and comprising a sequence of interest to be expressed from said RNA replicon; wherein the sequence encoding the RNA replicon has one or more segments that code together for said RNA replicon, whereby formation of said RNA replicon requires rearrangement of said segments.

#### **CLAIMS 1, 2, 10-12, AND 14-16 LINK THE INVENTIONS OF GROUPS I-IV**

Group V, claim(s) 21-28, drawn to a process of expressing a sequence of interest in a plant, plant part, or plant cell culture comprising providing a plant, plant part, or plant cell culture containing in cell nucleic a heterologous DNA having a sequence

Art Unit: 1638

encoding an RNA replicon derived from a plant RNA virus and comprising a sequence of interest to be expressed from said RNA replicon; wherein the sequence encoding the RNA replicon has one or more segments that code together for said RNA replicon, whereby formation of said RNA replicon requires rearrangement of said segments.

Group VI, claim(s) 29 and 30, drawn to a process of expressing a sequence of interest in a plant, plant part, or plant cell culture comprising providing a plant, plant part, or plant cell culture containing in cell nucleic a heterologous DNA having a sequence encoding an RNA replicon derived from a plant RNA virus and comprising a sequence of interest to be expressed from said RNA replicon; wherein the sequence endogen said RNA replicon is linked to a regulated transcription promoter.

**CLAIMS 17-20, 31-34, 47, 50, AND 51 LINK THE INVENTIONS OF GROUPS V, VI, AND IX-XVI**

Group VII, claim(s) 35, drawn to a process of producing a transgenic plant stably transformed on a nuclear chromosome with a heterologous DNA having a sequence encoding an RNA replicon derived from a plant RNA virus and comprising a sequence of interest to be expressed from said RNA replicon.

Group VIII, claim(s) 36-38, drawn to a process of transiently expressing a sequence of interest in a plant, plant part, or plant cell culture, comprising: transforming a plant, plant part, or plant cell culture with a heterologous DNA having a sequence encoding an RNA replicon derived from a plant RNA virus and comprising a sequence of interest to be expressed from said RNA replicon.

Group IX, claim(s) 39-42 and 48, drawn to a process of expressing a sequence of interest in a plant, plant part, or plant cell culture comprising providing a plant, plant part, or plant cell culture containing in cell nucleic a heterologous DNA having a sequence encoding an RNA replicon derived from a plant RNA virus and comprising a sequence of interest to be expressed from said RNA replicon; wherein selected localities of said RNA virus are localities of high A/U content.

Group X, claim(s) 43, drawn to a process of expressing a sequence of interest in a plant, plant part, or plant cell culture comprising providing a plant, plant part, or plant cell culture containing in cell nucleic a heterologous DNA having a sequence encoding an RNA replicon derived from a plant RNA virus and comprising a sequence of interest to be expressed from said RNA replicon; wherein cryptic splice sites flanking A/U-rich regions have been removed.

Group XI, claim(s) 44 and 45 drawn to a process of expressing a sequence of interest in a plant, plant part, or plant cell culture comprising providing a plant, plant part, or plant cell culture containing in cell nucleic a heterologous DNA having a sequence encoding an RNA replicon derived from a plant RNA virus and comprising a sequence of interest to be expressed from said RNA replicon; wherein there is an insertion of one or more nuclear introns.

Group XII, claim(s) 46, drawn to a process of expressing a sequence of interest in a plant, plant part, or plant cell culture comprising providing a plant, plant part, or plant cell culture containing in cell nucleic a heterologous DNA having a sequence encoding an RNA replicon derived from a plant RNA virus and comprising a sequence of interest to be expressed from said RNA replicon; wherein the sequence encoding the RNA replicon has one or more segments that code together for said RNA replicon, whereby formation of said RNA replicon requires rearrangement of said segments.

Group XIII, claim(s) 49, drawn to a process of expressing a sequence of interest in a plant, plant part, or plant cell culture comprising providing a plant, plant part, or plant cell culture containing in cell nucleic a heterologous DNA having a sequence encoding an RNA replicon derived from a plant RNA virus and comprising a sequence of interest to be expressed from said RNA replicon; wherein a selected

Art Unit: 1638

locality is identified by transforming a plant, plant part, or plant cell culture with said heterologous DNA, performing Rt-PCR, and identifying in the sequence of the RT-PCR product a selected locality.

Group XIV, claim(s) 52 and 54, drawn to a process of expressing a sequence of interest in a plant, plant part, or plant cell culture comprising providing a plant, plant part, or plant cell culture containing in cell nucleic a heterologous DNA having a sequence encoding an RNA replicon derived from a plant RNA virus and comprising a sequence of interest to be expressed from said RNA replicon; wherein the plant, plant part, or plant cell culture contains two or more different heterologous DNAs.

Group XV, claim(s) 53, drawn to a process of expressing a sequence of interest in a plant, plant part, or plant cell culture comprising providing a plant, plant part, or plant cell culture containing in cell nucleic a heterologous DNA having a sequence encoding an RNA replicon derived from a plant RNA virus and comprising a sequence of interest to be expressed from said RNA replicon; wherein the replicon is capable of exhibiting an increased frequency of replicon formation compared with the natural host plant of the RNA virus from which the replicon is derived.



Art Unit: 1638

Group XVI, claim(s) 55, drawn to a process of expressing a sequence of interest in a plant, plant part, or plant cell culture comprising providing a plant, plant part, or plant cell culture containing in cell nucleic a heterologous DNA having a sequence encoding an RNA replicon derived from a plant RNA virus and comprising a sequence of interest to be expressed from said RNA replicon; wherein the transforming of the plant, plant part, or plant cell culture is by infiltrating it with a suspension of Agrobacteria, said suspension having a concentration corresponding to a specific calculated optical density at 600 nm.

**CLAIMS 17-20, 31-34, 47, 50, AND 51 LINK THE INVENTIONS OF GROUPS V, VI, AND IX-XVI**

Group XVII, claim(s) 56, drawn to a process of expressing a sequence of interest in a plant, plant part, or plant cell culture, comprising transforming a plant, plant part, or plant cell culture with a suspension of Agrobacteria, said Agrobacteria containing in T-DNA a heterologous DNA having a sequence encoding a replicon, wherein said sequence encoding a replicon contains sequences for replicon function derived from a plant virus and a sequence of interest, and wherein the suspension of Agrobacteria has a concentration of cells corresponding to a specific calculated optical density at 600 nm.

Group XVIII, claim(s) 57, drawn to nucleic acid molecule containing a DNA sequence encoding an RNA replicon wherein said replicon contains sequences for replication function derived from a plant RNA virus and a sequence of interest to be expressed from said replicon.

2. Claims 1, 2, 10-12, and 14-16 link the inventions of groups I-IV. Claims 17-20, 31-34, 47, 50, and 51 link the inventions of groups V, VI, and IX-XVI. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claims. Upon the allowance of the linking claims, the restriction requirement as to the linked inventions shall be withdrawn and any claims depending from or otherwise including all the limitations of the allowable linking claims will be entitled to examination in the instant application. Applicants are advised that if any such claims depending from or including all the limitations of the allowable linking claims are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant applications. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP 804.01.

3. The inventions listed as Groups I-XVIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature linking groups I-XVIII is a nucleic acid molecule containing a DNA sequence encoding an RNA replicon wherein said replicon contains sequences for replication function derived from a plant RNA virus and a sequence of interest to be expressed from said replicon. However, in the prior art (Nature Biotechnology (2002) Vol. 20, pp. 622-625), Mallory et al teach a nucleic acid molecule containing the potato virus X (PVX) replicon carrying a gene of interest (see first paragraph). Therefore, the technical feature linking the inventions of groups I-XVIII does not constitute a special technical feature as defined by PCT Rule 13.2 as it does not define a contribution over the prior art.

Accordingly, Groups I-XVIII are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept.

4. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply

does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability

including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained.

Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to CATHY K. WORLEY whose telephone number is (571)272-8784. The examiner can normally be reached on M-F 10:00 - 4:00, with additional variable hours before 10:00 and after 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cathy K. Worley/  
Primary Examiner, Art Unit 1638